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REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

At the outset, Applicants wish to address the showing required by 37 CFR § 1.116(b) as to why this amendment is necessary and was not presented earlier. This amendment is responsive to a new ground of rejection in the final rejection, and is necessary to remove this new ground of rejection. Since this is the first substantive response to the final rejection, obviously this amendment could not have been presented earlier. Therefore, Applicants respectfully request that the Examiner enter and consider this amendment.

Claim 9 was rejected under 35 USC § 112, second paragraph, as being indefinite. In response, Applicants have amended claim 9 to recite what was originally intended, i.e., a method of treating a *bacterial* infection.

Claims 1, 2, 4, 5, 7 and 8 were rejected under 35 USC § 103(a) as being obvious over Franz et al. ("Franz"), US 5,797,873.

Claim 3 was rejected under 35 USC § 103(a) as being obvious over Franz in view of Pietsch, US 4,588,583.

Claim 6 was rejected under 35 USC § 103(a) as being obvious over Franz in view of Pratt et al. ("Pratt"), US 4,283,799.

Claim 9 was rejected under 35 USC § 103(a) as being obvious over Franz in view of Salaria, *Indian Pediatrics*, 38: 372-375 (2001).

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In response to *all four* obviousness rejections, Applicants again respectfully submit that the Examiner has not made out a *prima facie* case of obviousness. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw these rejections.

In the last sentence on page 4 of the Office Action, the Examiner cites to the decision in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980). This is to support a statement made by the Examiner earlier in the same paragraph, viz.:

“The motivation for combining them flows from their *having been* used individually in the prior art, and from them *being recognized in the prior art* as useful for the same purpose.”

Similar language can be found in *Kerkhoven* at page 1072.

A problem with the Examiner's attempt to rely on *Kerkhoven* here is that the Examiner has not demonstrated that what he says it would have been obvious to combine, given *Kerkhoven*, was known in the prior art, or recognized in the prior art as useful for the indicated purpose. Thus, while Franz mentions teicoplanin, gentamicin, clindamycin and vancomycin, Franz does not teach either powdery teicoplanin or powdery, water-soluble salts of gentamicin, clindamycin and vancomycin, which, in actuality, are what must “have been used individually in the prior art,” and must have “recognized in the prior art as useful for the same purpose” in order for the obviousness of their combination to fit in under *Kerkhoven*'s umbrella.

What the Examiner does is make a *first* hypothetical finding that powdery teicoplanin would have been obvious, and a *second* hypothetical finding that powdery

gentamicin, clindamycin and vancomycin would have been obvious, and then a *third* further hypothetical finding that powdery, water-soluble salts of gentamicin, clindamycin and vancomycin would also have been obvious, and only then apply Kerkhoven's premise, devoid of the underlying logic adduced above, to come to a *fourth* hypothetical finding that a combination of powdery teicoplanin and at least one powdery, water-soluble salt of gentamicin, clindamycin and vancomycin would also have been expected to be obvious. Respectfully, there are simply too many layers of supposition—one on top of another on top of another on top of yet another—for this rejection to be tenable. The present rejection is not supported by the *Kerkhoven* logic, but, rather, runs far a field of it. Applicants respectfully submit that this is a classic hindsight rejection, which is improperly based on Applicants' disclosure and not the cited prior art and, therefore, must be withdrawn.

Granted, all prior art rejections are to some extent based on hindsight. However, impermissible hindsight occurs where selections are made not based solely on the cited references. This is what has occurred here. There is no express teaching in Franz that teicoplanin is used in a powdered form, and this is not inherent. (The Examiner uses the word "implicit," which has no legal correctness here. Disclosures are either express or inherent, and to be inherent, a disclosure must necessarily result from the prior art teachings. See, *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), for the proposition that inherency is not established by probabilities or possibilities, and the mere fact that a property may result from a given circumstances is not sufficient; instead it must be shown that such property *necessarily* inheres in the thing described in the reference.) It is certainly not the case that, in the context of Franz's teachings,

teicoplanin must necessarily be used in powdered form. Consequently, there is neither an express teaching nor an inherent teaching in Franz of powdered teicoplanin.

In like manner, there is no express or inherent teaching in Franz of powdered gentamicin, clindamycin and vancomycin, let alone of a powdered, water-soluble salt thereof. The Examiner has made a very colorful case why these forms would have been obvious, but such does not flow from the teachings of the prior art so, as a matter of law, they would not have been obvious.

Obviously, the Examiner views what Applicants have done as something rather straight-forward and routine. However, it is exactly in such situations that greater care must be taken to guard against prejudice induced by the simplicity of what Applicants have done.

As stated in *In re Dembiczak*, 175 F.3d 994, 50 USPQ2d 1614, (Fed. Cir. 1999):

“Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of the invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one ‘to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against the teacher.’...Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness

analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. [Emphasis added.]”

Applicants submit that when a rigorous application of the requirement of a proper teaching or motivation to combine is made in the instant case, the Examiner’s house of cards folds. There simply is no way that a person having ordinary skill in the art, having to make all the selections and modifications in Franz’s disclosure that must be made in order to achieve the present invention, would actually have been led by Franz to make such selections and modifications to achieve the present invention with a reasonable expectation of success.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,
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